Supplementary appendix 2

Table of Contents **Page**

This supplementary material has been provided by the authors to give readers additional information about their work.

Table S1. Inclusion and Exclusion Criteria.

Inclusion criteria
1. Skeletally mature patients (16 years or older) men or women
2. Isolated Weber B -type fibula fracture and no widening of the ankle mortise on the static ankle radiographs Medial clear space < 4 mm and ≤ 1 mm wider than the superior clear space
3. Stable ankle mortise at the External-Rotation Stress test (ER-stress) Medial Clear Space (MCS) < 5 mm as measured between the lateral border of the medial malleolus and the medial border of the talus at the level of the talar dome
4. Patients able to walk unaided before the current trauma
5. The enrolment less than 7 days after the injury
6. Provision of informed consent from the participant
Exclusion criteria
1. Previous ankle fracture or deltoid ligament injury or other significant fracture in the ankle/foot area
2. Bilateral ankle fracture
3. Concomitant tibial fracture
4. Pathological fracture
5. Diabetic or other neuropathy
6. Inadequate co-operation Inability to speak, understand and read in the language of the clinical site (history of alcoholism, drug abuse, psychological or psychiatric problems that are likely to invalidate informed consent
7. Permanent residence outside the catchment area of the hospital
8. Patient declined to participate

Table S2. Intention-to-treat (ITT) analysis of the primary outcome, the Olerud-Molander Ankle Score (OMAS*).

The two panels below provide the data on the two primary comparisons. The data is presented as mean (SD) and the mean between-group difference (with 95% confidence interval). The upper panel provides the 3-week cast vs. 6-week cast comparison and the lower panel provides the 3-week orthosis vs. 6-week cast comparison. **A <u>positive</u> "Difference" means that the participants in the comparator (i.e., 6-week cast) group reported <u>more</u> (severe) symptoms at the 6-, 12 -and 52-week time points.** The analyses were carried out using a repeated measures mixed model (RMMM) ANOVA.

Variable	At 6 weeks			At 12 weeks			At 52 weeks		
OMAS	No.	Mean (SD)	Difference, Mean (95% CI)	No.	Mean (SD)	Difference, Mean (95% CI)	No.	Mean (SD)	Difference, Mean (95% CI)
3-week cast	82	54 (18)	-4.8 (-11.2 to 1.5)	75	73 (19)	7.2 (0.2 to 14.1)	73	92 (13)	3.6 (-1.9 to 9.1)
vs.									
6-week cast	74	60 (21)		70	69 (23)		73	88 (18)	
3-week orthosis	78	55 (20)	-4.0 (-10.3 to 2.5)	73	70 (21)	3.5 (-3.5 to 10.5)	66	90 (18)	1.7 (-4.0 to 7.3)
vs.									
6-week cast	74	60 (21)		70	69 (23)		73	88 (18)	

*OMAS values range from 0 to 100, with lower scores indicating more severe symptoms.

Table S3. Per protocol (PP) analysis of the primary outcome, the Olerud-Molander Ankle Score (OMAS*).

The two panels below provide the data on the two primary comparisons. The data is presented as mean (SD) and the mean between-group difference (with 95% confidence interval). The upper panel provides the 3-week cast vs. 6-week cast comparison and the lower panel provides the 3-week orthosis vs. 6-week cast comparison. **A <u>positive</u> "Difference" means that the participants in the comparator (i.e., 6-week cast) group reported <u>more</u> (severe) symptoms at the 6-, 12 -and 52-week time points.** The analyses were carried out using a repeated measures mixed model (RMMM) ANOVA.

Variable	At 6 weeks			At 12 weeks			At 52 weeks		
OMAS	No.	Mean (SD)	Difference, Mean (95% CI)	No.	Mean (SD)	Difference, Mean (95% CI)	No.	Mean (SD)	Difference, Mean (95% CI)
3-week cast	82	54 (18)	-4.1 (-10.5 to 2.3)	75	73 (19)	8.0 (0.9 to 15.1)	73	92 (13)	4.3 (-1.2 to 9.9)
vs.									
6-week cast	71	59 (20)		67	68 (23)		70	87 (18)	
3-week orthosis	78	55 (20)	-3.2 (-9.6 to 3.2)	73	73 (19)	4.3 (-2.9 to 11.4)	66	90 (18)	2.4 (-3.3 to 8.1)
vs.									
6-week cast	71	59 (20)		67	68 (23)		70	87 (18)	

*OMAS values range from 0 to 100, with lower scores indicating more severe symptoms.

Table S4. Intention-to-treat (ITT) analysis of the secondary outcome, the Foot and Ankle Outcome Score (FAOS*).

The two panels below provide the data (both interim and primary time points) on the two primary comparisons. The data is presented as mean (SD) (all time points) and the mean between-group difference (with 95% confidence interval) (only primary time point, 52 weeks). The upper panel provides the 3-week cast vs. 6-week cast comparison and the lower panel provides the 3-week orthosis vs. 6-week cast comparison. **A <u>positive</u> "Difference" means that the participants in the comparator (i.e., 6-week cast) group reported <u>lower</u> ankle function / <u>more</u> severe symptoms at the 52-week time point**.** The analyses were carried out using a repeated measures mixed model (RMMM) ANOVA.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
FAOS	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Pain							
3-week cast	78	73 (14)	74	84 (13)	73	95 (8)	2.0 (-1.2 to 5.3)
vs.							
6-week cast	72	82 (15)	67	79 (16)	73	92 (12)	
3-week orthosis	75	71 (15)	71	79 (15)	66	91 (16)	-1.8 (-6.3 to 2.6)
vs.							
6-week cast	72	82 (15)	67	79 (16)	73	92 (12)	
Symptoms							
3-week cast	78	62 (20)	74	73 (21)	73	87 (15)	2.6 (-2.5 to 7.8)
vs.							
6-week cast	72	63 (23)	67	68 (21)	72	84 (17)	
3-week orthosis	75	61 (22)	70	70 (21)	66	84 (21)	0.1 (-6.2 to 6.4)
vs.							
6-week cast	72	63 (23)	67	68 (21)	72	84 (17)	

Table S4, cont.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
FAOS	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Activity and daily living							
3-week cast	78	81 (12)	74	92 (12)	73	97 (7)	2.1 (-0.9 to 5.1)
vs.							
6-week cast	72	80 (17)	67	89 (16)	72	94 (12)	
3-week orthosis	75	79 (18)	70	86 (16)	65	94 (15)	-0.8 (-5.1 to 3.5)
vs.							
6-week cast	72	80 (17)	67	89 (16)	72	94 (12)	
Sport and recreation function							
3-week cast	75	47 (24)	73	70 (25)	73	91 (18)	6.2 (-0.9 to 13.4)
vs.							
6-week cast	70	42 (28)	66	61 (27)	72	84 (25)	
3-week orthosis	72	43 (27)	69	65 (28)	65	88 (24)	3.5 (-3.8 to 10.8)
vs.							
6-week cast	70	42 (28)	66	61 (27)	72	84 (25)	
Quality of life							
3-week cast	78	46 (18)	74	66 (23)	73	88 (16)	2.2 (-4.1 to 8.5)
vs.							
6-week cast	72	47 (24)	69	60 (27)	73	85 (22)	
3-week orthosis	75	46 (20)	71	62 (23)	66	85 (20)	0.5 (-6.0 to 7.0)
vs.							
6-week cast	72	47 (24)	69	60 (27)	73	85 (22)	

* FAOS, 5 subscales, values range from 0 to 100, with lower scores indicating more severe symptoms

** For secondary outcomes, between-group comparisons (3-week cast vs. 6-week cast and 3-week orthosis vs. 6-week cast) were only performed at the primary 52-week time point.

Table S5. Intention-to-treat (ITT) analysis of the secondary outcome, the Visual Analogue Scale (VAS*).

The two panels below provide the data (both interim and primary time points) on the two primary comparisons. The data is presented as mean (SD) (all time points) and the mean between-group difference (with 95% confidence interval) (only primary time point, 52 weeks). The upper panel provides the 3-week cast vs. 6-week cast comparison and the lower panel provides the 3-week orthosis vs. 6-week cast comparison. **A <u>positive</u> "Difference" means that the participants in the comparator (i.e., 6-week cast) group reported <u>more</u> pain/<u>lower</u> function at the 52-week time point**.** The analyses were carried out using a repeated measures mixed model (RMMM) ANOVA.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
VAS	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Pain							
3-week cast	77	28 (22)	72	18 (21)	72	7 (12)	
vs.							-2.9 (-8.0 to 2.3)
6-week cast	70	19 (19)	70	21 (21)	72	10 (18)	
3-week orthosis	75	30 (22)	72	24 (23)	66	9 (17)	
vs.							-0.6 (-5.8 to 4.7)
6-week cast	70	19 (19)	70	21 (21)	72	10 (18)	
Function							
3-week cast	77	38 (24)	72	20 (23)	70	7 (10)	
vs.							-4.6 (-9.9 to 0.8)
6-week cast	70	49 (28)	70	26 (24)	72	11 (20)	
3-week orthosis	74	40 (23)	72	28 (24)	65	9 (17)	
vs.							-1.5 (-7.1 to 4.0)
6-week cast	70	49 (28)	70	26 (24)	72	11 (20)	

* VAS (pain and function), range from 0 to 100, with higher scores indicating more severe pain and decreased ankle function
** For secondary outcomes, between-group comparisons (3-week cast vs. 6-week cast and 3-week orthosis vs. 6-week cast) were only performed at the primary 52-week time point.

Table S6. Intention-to-treat (ITT) analysis of the secondary outcome, the RAND 36-Item Health Survey (RAND-36*).

The two panels below provide the data (both interim and primary time points) on the two primary comparisons. The data is presented as mean (SD) (all time points) and the mean between-group difference (with 95% confidence interval) (only primary time point, 52 weeks). The upper panel provides the 3-week cast vs. 6-week cast comparison and the lower panel provides the 3-week orthosis vs. 6-week cast comparison. **A <u>positive</u> "Difference" means that the participants in the comparator (i.e., 6-week cast) group reported lower health related quality of life at the 52-week time point**.** The analyses were carried out using a repeated measures mixed model (RMMM) ANOVA.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
RAND 36	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Physical function							
3-week cast	79	61 (21)	74	77 (22)	73	89 (17)	1.1 (-5.1 to 7.4)
vs.							
6-week cast	76	49 (29)	70	74 (25)	71	87 (20)	
3-week orthosis	77	58 (28)	72	72 (24)	66	86 (22)	-1.9 (-8.2 to 4.5)
vs.							
6-week cast	76	49 (29)	70	74 (25)	71	87 (20)	
General health							
3-week cast	79	74 (20)	74	74 (21)	73	74 (21)	-0.0 (-6.6 to 6.5)
vs.							
6-week cast	76	72 (18)	70	72 (19)	71	74 (22)	
3-week orthosis	77	73 (20)	72	70 (21)	66	71 (21)	-3.2 (-9.9 to 3.4)
vs.							
6-week cast	76	72 (18)	70	72 (19)	71	74 (22)	

Table S6, cont.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
RAND 36	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Mental health							
3-week cast	79	74 (18)	74	81 (17)	73	82 (15)	0.4 (-4.2 to 4.9)
vs.							
6-week cast	76	74 (17)	70	79 (14)	71	82 (15)	
3-week orthosis	76	74 (21)	71	80 (17)	66	85 (13)	3.6 (-1.0 to 8.3)
vs.							
6-week cast	76	74 (17)	70	79 (14)	71	82 (15)	
Role function (physical)							
3-week cast	79	23 (35)	74	66 (42)	73	86 (29)	-0.3 (-10.2 to 9.6)
vs.							
6-week cast	76	20 (31)	70	54 (44)	71	86 (30)	
3-week orthosis	77	24 (35)	71	59 (42)	66	85 (33)	-1.3 (-11.5 to 8.9)
vs.							
6-week cast	76	24 (35)	70	59 (42)	71	86 (30)	
Vitality							
3-week cast	79	65 (21)	74	72 (20)	73	76 (17)	0.1 (-5.5 to 5.7)
vs.							
6-week cast	75	64 (20)	70	69 (18)	71	75 (18)	
3-week orthosis	77	64 (21)	72	71 (20)	66	76 (17)	0.8 (-4.9 to 6.6)
vs.							
6-week cast	75	64 (20)	70	69 (18)	71	75 (18)	

Table S6, cont.

Variable	At 6weeks		At 12 weeks		At 52 weeks		
RAND 36	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Bodily pain							
3-week cast	79	50 (22)	74	68 (23)	73	83 (19)	3.4 (-3.8 to 10.6)
vs.							
6-week cast	76	61 (24)	70	63 (23)	71	78 (23)	
3-week orthosis	77	48 (22)	71	65 (20)	66	81 (23)	1.7 (-5.7 to 9.1)
vs.							
6-week cast	76	61 (24)	70	63 (23)	71	78 (23)	
Social Function							
3-week cast	79	67 (23)	74	87 (18)	73	91 (15)	2.8 (-2.5 to 8.0)
vs.							
6-week cast	76	63 (25)	70	79 (24)	71	89 (19)	
3-week orthosis	77	63 (27)	71	84 (20)	66	93 (13)	4.7 (-0.7 to 10.1)
vs.							
6-week cast	76	63 (25)	70	79 (24)	71	89 (19)	
Role function (emotional)							
3-week cast	79	58 (43)	74	85 (31)	73	87 (29)	0.0 (-9.2 to 9.3)
vs.							
6-week cast	76	53 (42)	70	75 (39)	71	87 (28)	
3-week orthosis	77	64 (41)	71	80 (36)	66	91 (26)	3.1 (-6.4 to 12.6)
vs.							
6-week cast	76	53 (42)	70	75 (39)	71	87 (28)	

* RAND-36, 8 subscales, values range from 0 to 100, with higher scores indicating better health related quality of life

** For secondary outcomes, between-group comparisons (3-week cast vs. 6-week cast and 3-week orthosis vs. 6-week cast) were only performed at the primary 52-week time point.

Table S7. Intention-to-treat (ITT) analysis of the secondary outcome, the Range-of-motion (ROM) of the injured ankle (ROM*).

The two panels below provide the data (both interim and primary time points) on the two primary comparisons. The data is presented as mean (SD) (all time points) and the mean between-group difference (with 95% confidence interval) (only primary time point, 52 weeks). The upper panel provides the 3-week cast vs. 6-week cast comparison and the lower panel provides the 3-week orthosis vs. 6-week cast comparison. **A <u>positive</u> "Difference" means that the participants in the comparator (i.e., 6-week cast) group reported had <u>lower</u> dorsi- and/or plantarflexion of the injured ankle at the 52-week time point**.** The analyses were carried out using a repeated measures mixed model (RMMM) ANOVA.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
ROM	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Ankle dorsiflexion, degree							
3-week cast	82	17 (8)	75	21 (9)	73	25 (9)	1.3 (-1.7 to 4.3)
vs.							
6-week cast	81	13 (8)	73	19 (10)	73	24 (9)	
3-week orthosis	78	18 (8)	73	21 (10)	66	25 (10)	0.5 (-2.6 to 3.6)
vs.							
6-week cast	81	13 (8)	73	19 (10)	73	24 (9)	
Ankle plantarflexion, degree							
3-week cast	82	41 (10)	75	48 (9)	73	53 (8)	1.9 (-0.8 to 4.7)
vs.							
6-week cast	81	35 (10)	73	46 (8)	73	51 (8)	
3-week orthosis	78	41 (10)	73	48 (8)	66	53 (8)	3.0 (0.2 to 5.8)
vs.							
6-week cast	81	35 (10)	73	46 (8)	73	51 (8)	

* Range-of-motion (ROM) of the injured ankle measured using a goniometer

** For secondary outcomes, between-group comparisons (3-week cast vs. 6-week cast and 3-week orthosis vs. 6-week cast) were only performed at the primary 52-week time point.

Table S8. Intention-to-treat (ITT) analysis of the secondary outcome, the incidence of fracture nonunion (fracture union)*.

The two panels below provide the data on the two primary comparisons. The data is presented as the mean between-group difference (with 95% confidence interval), at 52 weeks (primary time point). The upper panel provides the 3-week cast vs. 6-week cast comparison and the lower panel provides the 3-week orthosis vs. 6-week cast comparison. **A <u>positive</u> "Difference" means that the participants in the comparator (i.e., 6-week cast) group had <u>lower</u> incidence of the fracture non-union 52-week time point**.** Wilson method was used for calculating 95% confidence intervals.

Variable	At 52 weeks		
Fracture nonunion	No	Nonunion, No (%)	Difference, (percentage points) (95% CI)
3-week cast vs. 6-week cast	72 71	2 (2.8) 0 (0)	2.8 (-2.7 to 9.6)
3-week orthosis vs. 6-week cast	66 71	0 (0) 0 (0)	0.0 (-5.1 to 5.5)

* Fracture union was considered complete when the fracture line disappeared, and conversely, a visible fracture line designated a non-union.
** For secondary outcomes, between-group comparisons (3-week cast vs. 6-week cast and 3-week orthosis vs. 6-week cast) were only performed at the primary 52-week time point.

Table S9. Per protocol (PP) analysis of the secondary outcome, the Foot and Ankle Outcome Score (FAOS*).

The two panels below provide the data (both interim and primary time points) on the two primary comparisons. The data is presented as mean (SD) (all time points) and the mean between-group difference (with 95% confidence interval) (only primary time point, 52 weeks). The upper panel provides the 3-week cast vs. 6-week cast comparison and the lower panel provides the 3-week orthosis vs. 6-week cast comparison. **A <u>positive</u> "Difference" means that the participants in the comparator (i.e., 6-week cast) group reported <u>lower</u> ankle function / <u>more</u> severe symptoms at the 52-week time point**.** The analyses were carried out using a repeated measures mixed model (RMMM) ANOVA.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
FAOS	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Pain							
3-week cast	78	73 (14)	74	84 (13)	73	95 (8)	
vs.							2.3 (-1.7 to 6.2)
6-week cast	69	82 (15)	64	79 (16)	70	92 (12)	
3-week orthosis	75	71 (15)	71	79 (15)	66	91 (16)	
vs.							-1.5 (-5.5 to 2.5)
6-week cast	69	82 (15)	64	79 (16)	70	92 (12)	
Symptoms							
3-week cast	78	62 (20)	74	73 (21)	73	87 (15)	
vs.							3.1 (-2.2 to 8.3)
6-week cast	69	63 (23)	64	67 (21)	69	84 (17)	
3-week orthosis	75	61 (22)	70	70 (21)	66	84 (21)	
vs.							0.6 (-5.8 to 7.0)
6-week cast	69	63 (23)	64	67 (21)	69	84 (17)	

Table S9, cont.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
FAOS	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Activity and daily living							
3-week cast	78	81 (12)	74	92 (12)	73	97 (7)	2.4 (-0.7 to 5.4)
vs.							
6-week cast	69	79 (17)	64	89 (16)	69	94 (12)	
3-week orthosis	75	79 (18)	70	86 (16)	65	94 (15)	-0.5 (-4.9 to 3.9)
vs.							
6-week cast	69	79 (17)	64	89 (16)	69	94 (12)	
Sport and recreation function							
3-week cast	75	47 (24)	73	70 (25)	73	91 (18)	7.1 (-0.2 to 14.4)
vs.							
6-week cast	67	40 (27)	63	61 (27)	69	83 (26)	
3-week orthosis	72	43 (27)	69	65 (28)	65	88 (24)	4.3 (-3.1 to 11.8)
vs.							
6-week cast	67	40 (27)	63	61 (27)	69	83 (26)	
Quality of life							
3-week cast	78	46 (18)	74	66 (23)	73	88 (16)	2.6 (-3.9 to 9.0)
vs.							
6-week cast	69	46 (24)	66	60 (28)	70	84 (22)	
3-week orthosis	75	46 (20)	71	62 (23)	66	85 (20)	0.9 (-5.7 to 7.4)
vs.							
6-week cast	69	46 (24)	66	60 (28)	70	84 (22)	

* FAOS, 5 subscales, values range from 0 to 100, with lower scores indicating more severe symptoms

** For secondary outcomes, between-group comparisons (3-week cast vs. 6-week cast and 3-week orthosis vs. 6-week cast) were only performed at the primary 52-week time point.

Table S10. Per protocol (PP) analysis of the secondary outcome, the Visual Analogue Scale (VAS*).

The two panels below provide the data (both interim and primary time points) on the two primary comparisons. The data is presented as mean (SD) (all time points) and the mean between-group difference (with 95% confidence interval) (only primary time point, 52 weeks). The upper panel provides the 3-week cast vs. 6-week cast comparison and the lower panel provides the 3-week orthosis vs. 6-week cast comparison. **A positive "Difference" means that the participants in the comparator (i.e., 6-week cast) group reported more pain/lower function at the 52-week time point**.** The analyses were carried out using a repeated measures mixed model (RMMM) ANOVA.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
VAS	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Pain							
3-week cast	77	28 (22)	72	18 (21)	72	7 (12)	
vs.							-3.2 (-8.4 to 1.9)
6-week cast	67	18 (20)	67	21 (21)	69	10 (18)	
3-week orthosis	75	30 (22)	72	24 (23)	66	9 (17)	
vs.							-1.3 (-6.6 to 4.0)
6-week cast	67	18 (20)	67	21 (21)	69	10 (18)	
Function							
3-week cast	77	38 (24)	72	20 (23)	70	7 (10)	
vs.							-4.9 (-10.3 to 0.5)
6-week cast	67	49 (28)	67	26 (24)	69	11 (20)	
3-week orthosis	74	40 (23)	72	28 (24)	65	9 (17)	
vs.							-2.1 (-7.6 to 3.4)
6-week cast	67	49 (28)	67	26 (24)	69	11 (20)	

* VAS (pain and function), range from 0 to 100, with higher scores indicating more severe pain and decreased ankle function
** For secondary outcomes, between-group comparisons (3-week cast vs. 6-week cast and 3-week orthosis vs. 6-week cast) were only performed at the primary 52-week time point.

Table S11. Per protocol (PP) analysis of the secondary outcome, the RAND 36-Item Health Survey (RAND-36*).

The two panels below provide the data (both interim and primary time points) on the two primary comparisons. The data is presented as mean (SD) (all time points) and the mean between-group difference (with 95% confidence interval) (only primary time point, 52 weeks). The upper panel provides the 3-week cast vs. 6-week cast comparison and the lower panel provides the 3-week orthosis vs. 6-week cast comparison. **A <u>positive</u> "Difference" means that the participants in the comparator (i.e., 6-week cast) group reported lower health related quality of life at the 52-week time point**.** The analyses were carried out using a repeated measures mixed model (RMMM) ANOVA.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
RAND 36	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Physical function							
3-week cast	79	61 (21)	74	77 (22)	73	89 (17)	
vs.							1.8 (-4.5 to 8.1)
6-week cast	73	48 (29)	67	73 (25)	68	87 (20)	
3-week orthosis	77	58 (28)	72	72 (24)	66	86 (22)	
vs.							-1.2 (-7.7 to 5.2)
6-week cast	73	48 (29)	67	73 (25)	68	87 (20)	
General health							
3-week cast	79	74 (20)	74	74 (21)	73	74 (21)	
vs.							1.0 (-5.7 to 7.6)
6-week cast	73	72 (18)	67	72 (19)	68	74 (22)	
3-week orthosis	77	73 (20)	72	70 (21)	66	71 (21)	
vs.							-2.2 (-9.0 to 4.5)
6-week cast	73	72 (18)	67	72 (19)	68	74 (22)	

Table S11, cont.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
RAND 36	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Mental health							
3-week cast	79	74 (18)	74	81 (17)	73	82 (15)	0.4 (-4.3 to 5.0)
vs.							
6-week cast	73	74 (17)	67	79 (14)	68	82 (15)	
3-week orthosis	76	74 (21)	71	80 (17)	66	85 (13)	3.6 (-1.1 to 8.4)
vs.							
6-week cast	73	74 (17)	67	79 (14)	68	82 (15)	
Role function (physical)							
3-week cast	79	23 (35)	74	66 (42)	73	86 (29)	0.4 (-9.7 to 10.5)
vs.							
6-week cast	73	20 (31)	67	53 (44)	68	85 (31)	
3-week orthosis	77	24 (35)	71	59 (42)	66	85 (33)	-0.6 (-11.0 to 9.8)
vs.							
6-week cast	73	20 (31)	67	53 (44)	68	85 (31)	
Vitality							
3-week cast	79	65 (21)	74	72 (20)	73	76 (17)	-0.0 (-5.7 to 5.7)
vs.							
6-week cast	72	64 (20)	67	70 (18)	68	75 (18)	
3-week orthosis	77	64 (21)	72	71 (20)	66	76 (17)	0.7 (-5.1 to 6.5)
vs.							
6-week cast	72	64 (20)	67	70 (18)	68	75 (18)	

Table S11, cont.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
RAND 36	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Bodily pain							
3-week cast	79	50 (22)	74	68 (23)	73	83 (19)	4.6 (-2.7 to 11.9)
vs.							
6-week cast	73	61 (23)	67	63 (23)	68	77 (23)	
3-week orthosis	77	48 (22)	71	65 (20)	66	81 (23)	2.9 (-4.5 to 10.4)
vs.							
6-week cast	73	61 (23)	67	63 (23)	68	77 (23)	
Social Function							
3-week cast	79	67 (23)	74	87 (18)	73	91 (15)	2.7 (-3.0 to 8.4)
vs.							
6-week cast	73	63 (25)	67	79 (24)	68	89 (19)	
3-week orthosis	77	63 (27)	71	84 (20)	66	93 (13)	4.6 (-1.1 to 10.3)
vs.							
6-week cast	73	63 (25)	67	79 (24)	68	89 (19)	
Role function (emotional)							
3-week cast	79	58 (43)	74	85 (31)	73	87 (29)	0.1 (-9.3 to 9.5)
vs.							
6-week cast	73	53 (42)	67	74 (40)	68	87 (28)	
3-week orthosis	77	64 (41)	71	80 (36)	66	91 (26)	3.1 (-6.5 to 12.8)
vs.							
6-week cast	73	53 (42)	67	74 (40)	68	87 (28)	

* RAND-36, 8 subscales, values range from 0 to 100, with higher scores indicating better health related quality of life

** For secondary outcomes, between-group comparisons (3-week cast vs. 6-week cast and 3-week orthosis vs. 6-week cast) were only performed at the primary 52-week time point.

Table S12. Per Protocol (PP) analysis of the secondary outcome, the Range-of-motion (ROM) of the injured ankle (ROM*).

The two panels below provide the data (both interim and primary time points) on the two primary comparisons. The data is presented as mean (SD) (all time points) and the mean between-group difference (with 95% confidence interval) (only primary time point, 52 weeks). The upper panel provides the 3-week cast vs. 6-week cast comparison and the lower panel provides the 3-week orthosis vs. 6-week cast comparison. **A <u>positive</u> "Difference" means that the participants in the comparator (i.e., 6-week cast) group reported had <u>lower</u> dorsi- and/or plantarflexion of the injured ankle at the 52-week time point**.** The analyses were carried out using a repeated measures mixed model (RMMM) ANOVA.

Variable	At 6 weeks		At 12 weeks		At 52 weeks		
ROM	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	Difference, Mean (95% CI)
Ankle dorsiflexion, degree							
3-week cast	82	17 (8)	75	21 (9)	73	25 (9)	1.6 (-1.5 to 4.6)
vs.							
6-week cast	77	13 (7)	70	19 (10)	70	24 (9)	
3-week orthosis	78	18 (8)	73	21 (10)	66	25 (10)	0.8 (-2.3 to 4.0)
vs.							
6-week cast	77	13 (7)	70	19 (10)	70	24 (9)	
Ankle plantarflexion, degree							
3-week cast	82	41 (10)	75	48 (9)	73	53 (8)	1.9 (-0.8 to 4.7)
vs.							
6-week cast	77	34 (10)	70	46 (8)	70	50 (8)	
3-week orthosis	78	41 (10)	73	48 (8)	66	53 (8)	2.9 (0.1 to 5.7)
vs.							
6-week cast	77	34 (10)	70	46 (8)	70	50 (8)	

* Range-of-motion (ROM) of the injured ankle measured using a goniometer
** For secondary outcomes, between-group comparisons (3-week cast vs. 6-week cast and 3-week orthosis vs. 6-week cast) were only performed at the primary 52-week time point.

Table S13. Per Protocol Analysis of the secondary outcome, the incidence of fracture nonunion (fracture union)*.

The two panels below provide the data on the two primary comparisons. The data is presented as the mean between-group difference (with 95% confidence interval), at 52 weeks (primary time point). The upper panel provides the 3-week cast vs. 6-week cast comparison and the lower panel provides the 3-week orthosis vs. 6-week cast comparison. **A positive "Difference" means that the participants in the comparator (i.e., 6-week cast) group had lower incidence of the fracture non-union 52-week time point**.** Wilson method was used for calculating 95% confidence intervals.

Variable	At 52 weeks		
Fracture nonunion	No	Nonunion, No (%)	Difference, (percentage points) (95% CI)
3-week cast vs. 6-week cast	72 68	2 (2.8) 0 (0)	2.8 (-2.9 to 9.6)
3-week orthosis vs. 6-week cast	66 68	0 (0) 0 (0)	0.0 (-5.3 to 5.5)

* Fracture union was considered complete when the fracture line disappeared and conversely, a visible fracture line designated non-union.
** For secondary outcomes, between-group comparisons (3-week cast vs. 6-week cast and 3-week orthosis vs. 6-week cast) were only performed at the primary 52-week time point.

Table S14. Trial participants with symptomatic deep vein thrombosis

Treatment group	Diagnosis time point	DVT treatment	Control Doppler Ultrasound at the end of medical therapy	OMAS at 52 weeks
3-week cast	at 3 weeks	Coumadin	x	65
3-week cast	at 3 weeks	Coumadin	x	65
3-week cast	at 3 weeks	Coumadin	x	85
6-week cast	at 6 weeks	enoxaparin	x	60
6-week cast	at 6 weeks	Coumadin	x	100
6-week cast	at 6 weeks	enoxaparin	x	45
6-week cast	at 6 weeks	Coumadin	x	100
6-week cast	at 12 weeks	enoxaparin	x	90

Table S15. Sensitivity analyses (with ITT principle) of the primary outcome (OMAS, at 52 weeks) using linear regression model. The models in tables A-F are adjusted with different combination of baseline variables.

The estimated effect indicates the mean difference, 3-week (cast or orthosis) minus 6-week treatment.

A. Level of education*

	Estimated effect†	95 % CI	p-value
3-week cast	3.6	-1.8 to 9.0	0.19
3-week orthosis	2.1	-3.4 to 7.5	0.45

* Model is adjusted with the level of education (for details, see Table 1 of the main text)
† provides the mean treatment difference between the study groups.

B. Signs of medial injury*

	Estimated effect†	95 % CI	p-value
3-week cast	3.6	-1.8 to 9.0	0.19
3-week orthosis	2.1	-3.4 to 7.6	0.46

* Model is adjusted with the signs of medial injury (for details, see Table 1 of the main text)
† provides the mean treatment difference between the study groups.

C. Place of occurrence

	Estimated effect†	95 % CI	p-value
3-week cast	4.0	-1.4 to 9.3	0.14
3-week orthosis	2.1	-3.4 to 7.6	0.46

* Model is adjusted with the place of occurrence (for details, see Table 1 of the main text)
† provides the mean treatment difference between the study groups.

D. Level of education and signs of medial injury

	Estimated effect†	95 % CI	p-value
3-week cast	3.4	-2.0 to 8.8	0.21
3-week orthosis	2.1	-3.4 to 7.5	0.46

* Model is adjusted with the level of education and signs of medial injury (for details, see Table 1 of the main text)
† provides the mean treatment difference between the study groups.

E. Level of education and place of occurrence

	Estimated effect†	95 % CI	p-value
3-week cast	3.8	-1.5 to 9.1	0.16
3-week orthosis	2.1	-3.3 to 7.5	0.44

* Model is adjusted with the level of education and place of occurrence (for details, see Table 1 of the main text)
† provides the mean treatment difference between the study groups.

F. Level of education, signs of medial injury, and place of occurrence

	Estimated effect†	95 % CI	p-value
3-week cast	3.6	-1.8 to 8.9	0.19
3-week orthosis	2.1	-3.3 to 7.5	0.45

* Model is adjusted with the level of education, signs of medial injury, and place of occurrence (for details, see Table 1 of the main text).
† provides the mean treatment difference between the study groups.

Sample size calculation: A corrective note

In 2012, we used a following formula to calculate the original sample size:

$$n_A = \frac{(r+1)\sigma^2(Z_{1-\alpha} + Z_{1-\beta})^2}{r((\mu_A - \mu_B) - d)^2}$$

Where:

r=1, when equal n per group

σ^2 = estimated population variance; Our estimate for σ (20 points in the Olerud-Molander ankle score) was obtained from our previous trial[17] that included a virtually identical group of patients with a stable Weber B-type ankle fracture treated with cast immobilisation.

$(Z_{1-\alpha} + Z_{1-\beta})^2 = 7.9$, when α = 0.05 and β = 0.20 (power = 0.8)

μ_A = estimated true mean of treatment *A* (six-week cast); As above, our estimate for μ_A (88 points in the Olerud-Molander ankle score) was obtained from our previous trial[17].

μ_B = estimated true mean of treatment *B* (three-week orthosis or cast); Our estimate for μ_B (89 points in the Olerud-Molander ankle score) was based on previous comparative studies[12 18] that suggested that a treatment strategy of using a less rigid immobilisation would result in slightly (marginally) better outcome than conventional 6-weeks of casting. We decided that "marginally better" would mean 1 point in Olerud-Molander ankle score.

In this calculation, we used a value of 7.9, which comes from the equation:

$(Z_{1-\alpha/2} + Z_{1-\beta})^2$ with α=0.05 and β=0.2.

Now (September 2018), we have noticed that this value was erroneous; we should have used a value of 6.2 (instead of 7.9). The value 6.2 coming from the equation: $(Z_{1-\alpha} + Z_{1-\beta})^2$ with α=0.05 and β=0.2.

Using the dropout rate of 20% (used in the original sample size calculation and this correct value, the required sample size of 65 patients per group (total n=195) should have been recruited. In other words, the sample size recruited for this study (n=246) was larger than the minimum sample size required in accordance with the assumptions used when planning the trial.